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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,362	07/07/2003	Christopher J. M. Meade	1/1363	7889

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MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY RD
P O BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,362	MEADE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,34,35 and 37* is/are pending in the application.

4a) Of the above claim(s) *9-31 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 35, 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' amendment filed September 19, 2007 is acknowledged. Claim 36 is canceled. Claims 1-31 and 34, 35 and 37 remain under consideration. Claims 1-8, 35 and 37, drawn to pharmaceutical compositions and therapeutic methods, remain under consideration. Claims 9-31 and 34, drawn to non-elected subject matter, remain withdrawn from consideration, 37 CFR 1.142(b).

A Terminal Disclaimer filed September 19, 2007 is further acknowledged.

Applicants' arguments have been fully considered and are persuasive in part. Rejections or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant claims.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 4 contains the trade name Neuronorm.

Where a trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App.1982). The claim scope is uncertain since the trade namecannot always be used properly to identify any particular material. A trade name isused to identify a source of goods, and not the goods themselves. Thus, the trade name should be replaced with the actual chemical name.

Applicant's arguments with respect to claims 1-8 and 35-37 that were rejected under 35 U.S.C. 103(a) in the last Office Action as being unpatentable over Meissner et al., U.S. Patent No. 6,706,726, and Leroy et al., Expert Opinion on Investigational Drugs, have been considered but are moot in view of the new ground of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-8, 35 and 37 are rejected under 35 U.S.C. 103 as being unpatentable over Meissner et al., U.S. Patent No. 6,706,726, in view of Podolsky, D., U.S. 2003/185838.

Meissner teaches the administration of anticholinergic compounds of formula I wherein A forms an epoxy group, X^- is an anion, such as chloride, bromide, or methanesulphonate, R^1, R^2 and R^7 are methyl and the other R groups are hydrogen, to treat chronic obstructive pulmonary disease (COPD). See column 20, lines 14-15. As required by claims 35 and 37, see column 19, lines 60-65, where treatment of chronic obstructive pulmonary disease is disclosed. Podolsky teaches the administration of neurokinin receptor antagonists in the treatment of COPD. See page 3, as well as claims 5 and 16.

In view of the combined teachings of the cited prior art, the skilled artisan in pulmonology would have been motivated to combine an anticholinergic compound of

formula I and an NK_1 antagonist with a reasonable expectation of successfully treating a disease of the respiratory tract, such as chronic obstructive pulmonary disease. It is generally *prima facie* obvious to use in combination two or more agents that have previously been used separately for the same purpose. *In re Kerkhoven*, 205 USPQ 1069 (CCPA).

Specific statements in the references that would spell out the claimed invention are not necessary to show obviousness since questions of obviousness involve not only what references expressly teach, but rather what they would collectively suggest to one of ordinary skill in the art. *In re Burckel*, 201 USPQ 67 (CCPA).

With respect to the selection of a specific NK_1 antagonist, optimal proportions of the ingredients in the claimed compositions and an optimal dosage of the active agents in the instant compositions, it is not inventive to discover the optimum or workable ranges or preferred embodiments by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II). The determination of the optimum dosage regimen to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the

compound is administered a part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific dosage amounts and dosage regimens are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 26, 2007

Phyllis Spivack

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER